

JACIE Accreditation for Haematopoietic Stem Cell Transplant (HSCT) & Cellular Therapy Programmes: the EBMT Experience

Tuula Rintala, MSc, MBA

10th July 2024

What is JACIE?

- The Joint Accreditation Committee ISCT-Europe & EBMT (JACIE) is Europe's only official accreditation body in the field of haematopoietic stem cell transplantation (HSCT) and cellular therapy. It promotes high-quality patient care and medical and laboratory practice through a **profession-led, voluntary accreditation scheme**.
- <https://www.ebmt.org/jacie-accreditation>

Background

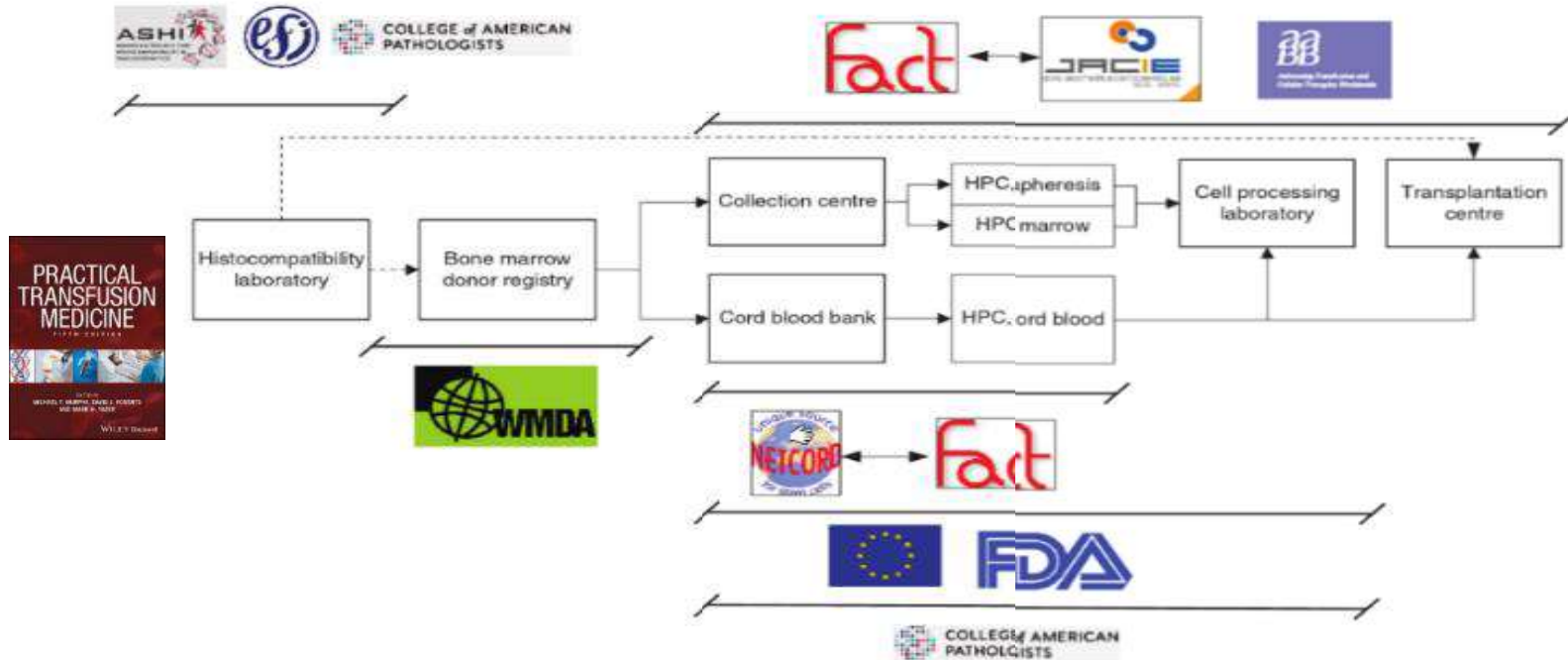


Figure 38.3 Regulatory environment for haematopoietic stem cell transplantation. Note that this figure does not reflect all potential regulatory reporting requirements for transplantation centres.

- “A self-assessment and external peer review process used by health and social care organisations to accurately assess their level of performance in relation to established standards and to implement ways to continuously improve the health or social care system”



ISQua Guidance on Designing
Healthcare External Evaluation
Programmes including
Accreditation (Oct 05 2015)

Standards

- Standards for Haematopoietic Stem Cell Transplantation and Cellular Therapy (co-published by FACT and JACIE)
- Based on consensus opinion by experts within the field (clinical, collection, processing)
- Scope of Standards:
 - Haematopoietic progenitor cells (HPCs)
 - Nucleated cells or mononuclear cells
 - Immune effector cells (IECs)
 - Genetically modified cells



Three Facets of Quality

Structure

- material characteristics (infrastructure, tools, technology) and resources of the organizations that provide care and the financing of care (levels of funding, staffing, payment schemes, incentives).

Process

- interaction between caregivers and patients during which structural inputs from the health care system are transformed into health outcomes.

Outcomes

- health status, deaths, or disability-adjusted life years—measure that encompasses the morbidity and mortality of patients or groups of patients.
- also include patient satisfaction or patient responsiveness to the health care system

Standards Structure

PART B CLINICAL	PART CM MARROW	PART C APHERESIS	PART D PROCESSING
B1 General	CM1 General	C1 General	D1 General
B2 Clinical Unit	CM2 Marrow Collection Facility	C2 Apheresis Collection Facility	D2 Processing Facility
B3 Personnel	CM3 Personnel	C3 Personnel	D3 Personnel
B4 Quality Management	CM4 Quality Management	C4 Quality Management	D4 Quality Management
B5 Policies and Standard Operating Procedures	CM5 Policies and Standard Operating Procedures	C5 Policies and Standard Operating Procedures	D5 Policies and Standard Operating Procedures
B6 Allogeneic and Autologous Donor Selection, Evaluation, and Management	CM6 Allogeneic and Autologous Donor Evaluation and Management	C6 Allogeneic and Autologous Donor Evaluation and Management	D6 Equipment, Supplies, and Reagents
B7 Recipient Care	CM7 Coding and Labeling of Cellular Therapy Products	C7 Coding and Labeling of Cellular Therapy Products	D7 Coding and Labeling of Cellular Therapy Products
	CM8 Process Controls	C8 Process Controls	D8 Process Controls
	CM9 Cellular Therapy Product Storage	C9 Cellular Therapy Product Storage	D9 Cellular Therapy Product Storage
	CM10 Cellular Therapy Product Transportation and Shipping	C10 Cellular Therapy Product Transportation and Shipping	D10 Cellular Therapy Product Transportation and Shipping
B8 Clinical Research			D11 Receipt and Distribution
B9 Data Management			D12 Disposal
B10 Records	CM11 Records	C11 Records	D13 Records
	CM12 Direct Distribution to Clinical Program	C12 Direct Distribution to Clinical Program	

Improving outcomes



ELSEVIER

Biology of Blood and Marrow Transplantation

journal homepage: www.bbmt.org

Bone Marrow Transplantation

[Explore our content](#) ▾ [Journal information](#) ▾

European Group for Blood and Marrow Transplantation Centers with FACT-JACIE Accreditation Have Significantly Better Compliance with Related Donor Care Standards

Chloe Anthias^{1,*}, Paul V. O'Donnell², Deidre M. Kiefer³, Jean Yared⁴, Maxim Norkin⁵, Paolo Anderlini⁶, Bipin N. Savani⁷, Miguel A. Diaz⁸, Menachem Bitan⁹, Joerg P. Halter¹⁰, Brent R. Logan^{11,12}, Galen E. Switzer¹³, Michael A. Pulsipher¹⁴, Dennis L. Confer¹⁵, Bronwen E. Shaw¹¹


[nature](#) > [bone marrow transplantation](#) > [features](#) > [article](#)
[Feature](#) | [Open Access](#) | [Published: 21 October 2019](#)

Benchmarking of survival outcomes following haematopoietic stem cell transplantation: A review of existing processes and the introduction of an international system from the European Society for Blood and Marrow Transplantation (EBMT) and the Joint Accreditation Committee of ISCT and EBMT (JACIE)

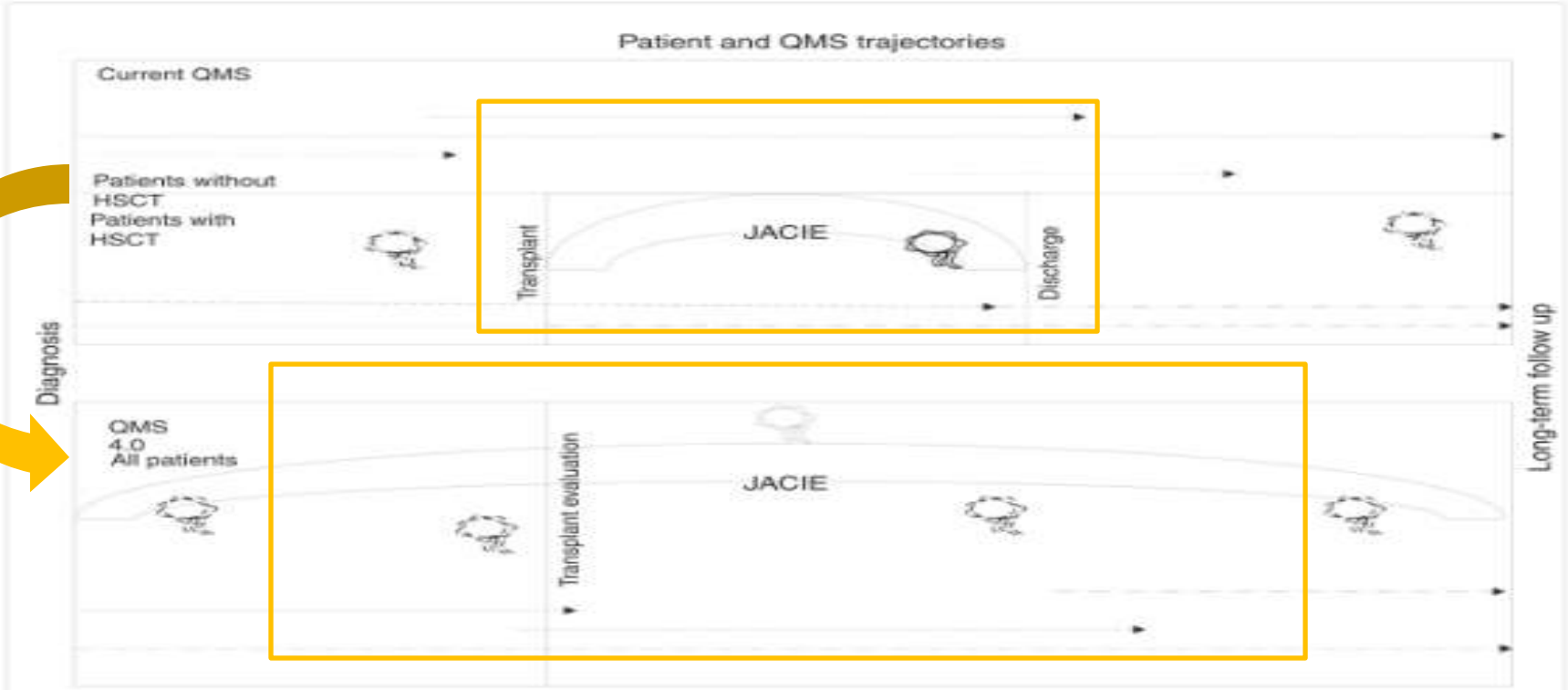
ARTICLES

Stem Cell Transplantation

Use of the quality management system "JACIE" and outcome after hematopoietic stem cell transplantation

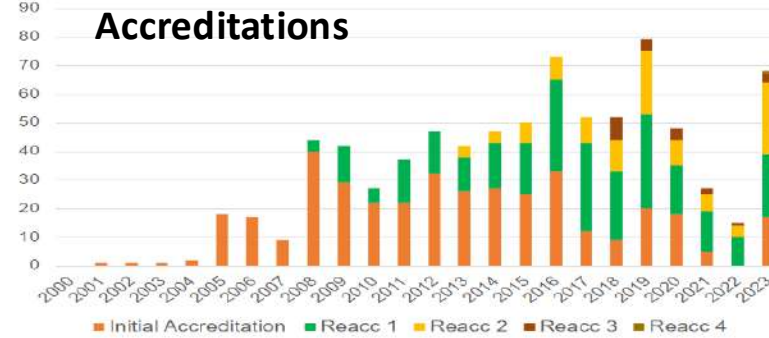
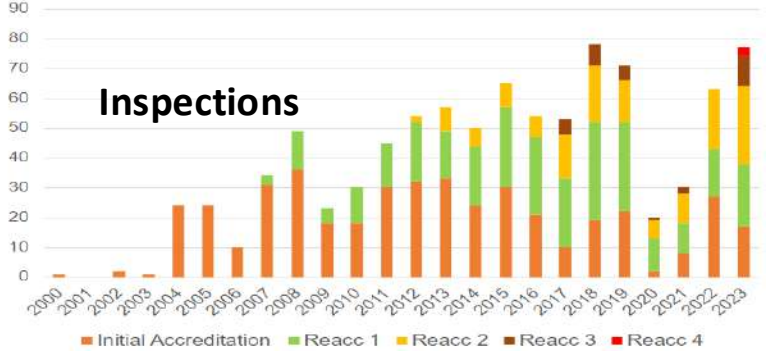
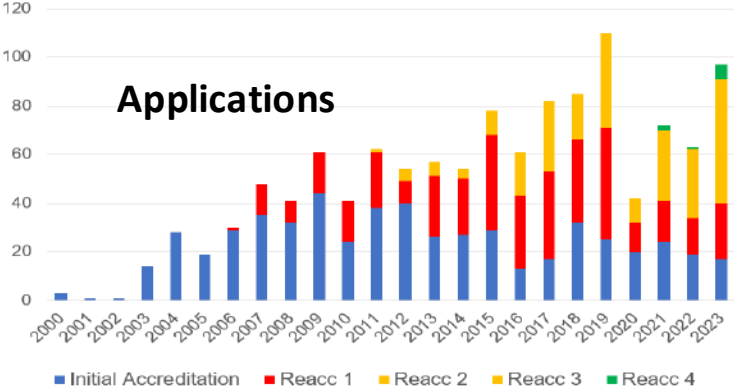
Alois Gratwohl,¹ Ronald Brand,² Eoin McGrath,³ Anja van Biezen,³ Anna Sureda,⁴ Per Ljungman,⁵ Helen Baldomero,⁶ Christian Chabannon,⁷ and Jane Apperley,⁸ for the Joint Accreditation Committee (JACIE) of the International Society for Cellular Therapy and the European Group for Blood and Marrow Transplantation, and the European Leukemia Net

Future for JACIE



Snowden, J.A., McGrath, E., Orchard, K. *et al.* Visions for a JACIE Quality Management System 4.0. *Bone Marrow Transplant* **56**, 2876–2881 (2021). <https://doi.org/10.1038/s41409-021-01467-8>

The first 25 years: JACIE Activity



More than 1,000 applications
 More than 800 inspections
 More than 700 Accreditations
 In 35 countries on five continents

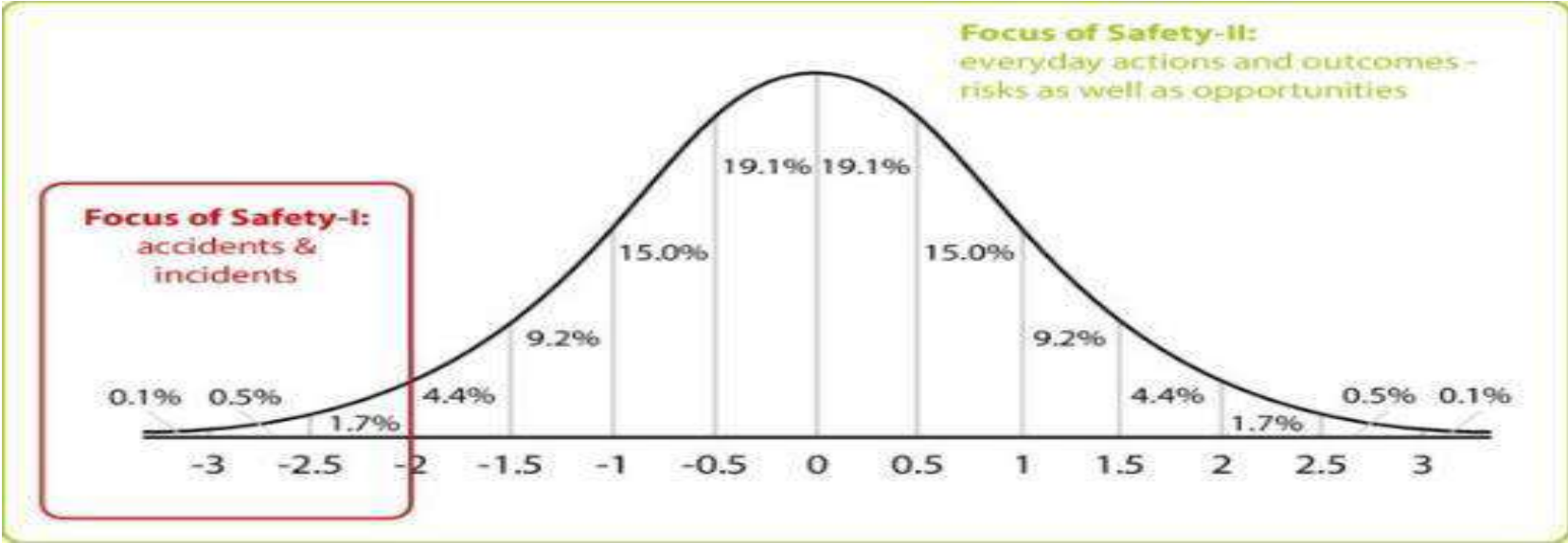
Thanks!

Any questions?

@TRintala

Tuula.Rintala@ebmt.org

Shift in Focus



	Safety-I	Safety-II
Definition of safety	That as few things as possible go wrong.	That as many things as possible go right.